Exhibit 11

Notice of Update to NIH Policies and Practices to Implement Executive Order 14168

Notice Number:
NOT-OD-25-140

Key Dates

Release Date:	

Related Announcements

- **September 23, 2024** - Updated Processes for Requesting Revisions to an Approved Data Management and Sharing (DMS) Plan. See Notice NOT-OD-24-176.
- **May 6, 2024** – Continued Extension of Certain Flexibilities for Prospective Basic Experimental Studies with Human Participants. See Notice NOT-OD-24-118.
- **February 26, 2003** – Final NIH Statement on Sharing Research Data. See Notice NOT-OD-03-032.
- **October 29, 2020** – Final NIH Policy for Data Management and Sharing. See Notice NOT-OD-21-013.
- **September 16, 2016** – NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information. See Notice NOT-OD-16-149.
- **August 27, 2014** – NIH Genomic Data Sharing Policy. See Notice NOT-OD-14-124.

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Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

This Guide notice notifies the research community of changes to NIH policies and practices to implement Executive Order 14168, "Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," sections 3(e) and 3(g), and the U.S. Department of Health and Human Services' (HHS) Sex-Based Definitions, and in alignment with the U.S. Office of Personnel Management (OPM) "Initial Guidance Regarding President Trump's Executive Order Defending Women" and the Office of Management and Budget (OMB) "Guidance on Implementing Section 3(e) of Executive Order 14168 in Accordance with the Paperwork Reduction Act and the Privacy Act."

Effective Date

This notice is effective on [30 days after publication date].

Scope and Applicability

This notice applies to all NIH-supported or conducted activities, whether supported by grants, contracts, other transactions, or NIH intramural funds (including the intramural research program), that are ongoing or initiated after the effective date of this notice.

This notice does not apply to NIH-supported or conducted activities collecting, receiving, or disseminating only non-human organism data.

Prohibition on Use of NIH Funds to Request, Collect, or Disseminate Information on Individuals' Gender

Pursuant to sections 3(e) and 3(g) of Executive Order 14168, NIH funding recipients and intramurally-supported activities (including research) shall not use NIH funds to request, collect, or disseminate information related to gender after the effective date, including for ongoing studies, unless required by applicable law or by limited exception (noted below). NIH funds may be used to request or collect information consistent with HHS's Sex-Based Definitions. NIH funds may be used to collect information in response to questions about sex to include information such as "unknown" or "don't know" if appropriate for the context of the collection, for example, if information is requested but not provided. Any forms approved by the Office of Management and Budget used for the collection of gender information used in NIH-supported or conducted activities must be revised consistent with the *Guidance on Implementing Section 3(e) of Executive Order 14168 in Accordance with the Paperwork Reduction Act and the Privacy Act*.

Additionally, pursuant to sections 3(e) and 3(g) of Executive Order 14168, NIH funding recipients and intramurally-supported activities (including research) shall not use NIH funds to submit gender information to publicly available databases or repositories, unless required by applicable law or by limited exception (noted below). Information submitted to such databases or repositories prior to the effective date may be finalized for public dissemination by such databases and repositories; this information is not expected to be removed. Information submitted to such databases and repositories but not yet publicly available before the effective date may be made publicly available without modification after the effective date. To ensure data integrity and understandability, database or repository guides for users, metadata, and other information provided by the database or repository related to historical data may be versioned, retained, and continue to be made publicly available, consistent with repository practice and/or statutory or regulatory requirements.

Limited exception: NIH funds may be used to collect information related to gender after the effective date when scientifically justified and in response to specific notices of funding opportunity as directed and approved by NIH. For research conducted by the NIH Intramural Research Program, the collection of gender information must be scientifically justified and the research approved by the Principal Deputy Director of NIH. NIH funds may be used to provide gender information in publicly available databases or repositories for qualifying studies.

Additional changes to NIH policies to implement sections 3(e) and 3(g) of Executive Order 14168 are provided below.[1]

Changes to Implementation of the *NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information* (NOT-OD-16-149)

This notice updates the implementation of the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149) to clarify that NIH-funded clinical trials, excluding those clinical trials considered applicable clinical trials[2], or as allowed by limited exception (noted above), shall not submit gender registration and results information to ClinicalTrials.gov; these trials shall continue to submit sex registration and results information. NIH-funded applicable clinical trials will continue to submit registration and results information to ClinicalTrials.gov in compliance with applicable law and regulatory reporting requirements.

Changes to Implementation of the *Final NIH Statement on Sharing Research Data* (NOT-OD-03-032), the *NIH Genomic Data Sharing Policy* (NOT-OD-14-124), and the *Final NIH Policy for Data Management and Sharing* (NOT-OD-21-013)

This notice updates the implementation of the Final NIH Statement on Sharing Research Data (NOT-OD-03-032), the NIH Genomic Data Sharing Policy (NOT-OD-14-124), and the Final NIH Policy for Data Management and Sharing (NOT-OD-21-013) to clarify that these policies will not expect sharing of gender information except for information consistent with the HHS Sex-Based Definitions. NIH funding recipients subject to these policies that have approved Data Management and Sharing Plans or Data Sharing Plans that propose the sharing of gender information may update their Plans to remove the sharing of gender information consistent with the process described in NOT-OD-24-176, unless gender information is required to be shared by law, and/or regulatory requirements, and/or allowable by limited exception (noted above).

Footnotes

[1] NIH is aware that the United States District Court for the Western District of Washington has issued a preliminary injunction that enjoined defendant agencies from enforcing or implementing section 4 of Executive Order 14187 within the Plaintiff States, as well as sections 3(e) or 3(g) of Executive Order 14168 to condition or withhold Federal funding based on the fact that a health care entity or health professional provides gender-affirming care within the Plaintiff States. *Washington v. Trump*, 768 F. Supp. 3d 1239, 1282 (W.D. Wash. 2025). The United States District Court for the District of Maryland has issued a preliminary injunction that enjoins the Federal defendants in that case from conditioning, withholding, or terminating Federal funding under section 3(g) of Executive Order 14168 and section 4 of Executive Order 14187, based on the fact that a healthcare entity or health professional provides gender affirming medical care to a patient under the age of nineteen and required a written notice instructing the aforementioned groups that Defendants may not take any steps to implement, give effect to, or reinstate under a different name the directives in section 3(g) of Executive Order 14168 or section 4 of Executive Order 14187 that condition or withhold Federal funding based on the fact that a healthcare entity or health professional provides gender affirming medical care to a patient under the age of nineteen. *PFLAG, Inc. v. Trump*, 769 F. Supp. 3d 405 (D. Md. 2025).

[2] The regulation, 42 CFR Part 11,defines an applicable clinical trial as “an applicable device clinical trial or an applicable drug clinical trial” as defined. An applicable device clinical trial means, in part, "a prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes)." The regulation defines an applicable drug clinical trial to mean, in part, "a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (42 U.S.C. 262), where "clinical investigation" has the meaning given in 21 CFR 312.3 (or any successor regulation) and "phase 1" has the meaning given in 21 CFR 312.21 (or any successor regulation).

Inquiries

Please direct all inquiries to:

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